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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,525	10/07/2002	Jamey D Marth	19452A-6-IUS	9242
20350	7590	10/28/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			ASHEN, JON BENJAMIN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,525	Applicant(s) MARTH ET AL.	
	Examiner Jon B. Ashen	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 6-12, drawn to a method of increasing levels of vWF or FVIII in an animal comprising administering an agent that increases ST3Gal-IV sialyltransferase activity in the animal.

Group II, claim(s) 1-12, drawn to a method of decreasing levels of vWF or FVIII in an animal comprising administering an agent that decreases ST3Gal-IV sialyltransferase activity in the animal.

Group III, claim(s) 13-17, drawn to a method of assaying the efficacy of a method of inhibiting ST3Gal-IV in a mammal comprising contacting cells obtained from said mammal with a binding moiety that specifically binds oligosaccharides having a terminal α 2,3, linked sialic acid.

Group IV, claim(s) 13-14 and 18-20, drawn to a method of assaying the efficacy of a method of inhibiting ST3Gal-IV in a mammal comprising contacting cells obtained from said mammal with a binding moiety that specifically binds oligosaccharides lacking a terminal α 2,3, linked sialic acid.

Group V, claim(s) 21-24 and 26-28 are drawn to a eukaryotic cell that comprises a non-naturally occurring mutation in an ST3Gal-IV allele(s) that results in a decrease in expression of the ST3Gal-IV allele(s) and a non-human chimeric or transgenic animal.

Group VI, claim(s) 21-23 and 25-28, drawn to a eukaryotic cell that comprises a non-naturally occurring mutation in an ST3Gal-IV allele(s) that results in a decrease in enzymatic activity of a ST3Gal-IV polypeptide expressed from a ST3Gal-IV allele(s) and a non human chimeric or transgenic animal.

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2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The special technical feature linking groups I-VIII is considered to be a method of modulating the levels of vWF or FVIII in an animal comprising administering an agent that modulates ST3Gal-IV sialyltransferase activity in an animal.

4. However, this application contains claims to different categories of invention that are not considered to have unity of invention because they are drawn to combinations of categories of inventions that are not set forth in 37 CFR 1.475 (b). In particular, as set forth in 37 CFR 1.475(c), this application contains claims to more than one of the combinations of categories of invention as set forth in 37 CFR 1.475(b). Because this application contains claims to multiple processes, the first invention of the category first mentioned in the claims (a process) and the first recited invention of each of the other categories related thereto will be considered the main invention. It is noted herein that the main invention is a process, said process being a method of modulating the levels of vWF or FVIII in an animal comprising administering an agent that modulates ST3Gal-IV sialyltransferase activity in an animal, and that no claims appear in this application to a product to be used in this process or to a process of making said product. Therefore, the process as first set forth and claimed in claim 1 is considered the main invention of this application.

The special technical feature of the main invention is set forth in (3) above and is not shared by the methods of groups IV and V that are drawn to methods of assaying the efficacy of a method of inhibiting ST3Gal-IV in a mammal comprising contacting cells obtained from said mammal with a binding moiety that specifically binds oligosaccharides having a terminal α 2,3, linked sialic acid (IV) or comprising contacting cells obtained from said mammal with a binding moiety that specifically binds oligosaccharides lacking a terminal α 2,3, linked sialic acid (V). Although the methods of groups IV and V relate to ST3Gal-IV activity, they do not share the special technical feature of administering an agent to an animal that modulates the levels of vWF or FVIII in said animal by modulating ST3Gal-IV activity. Groups IV and V share a different special technical feature which is an *in vitro* method of monitoring the efficacy of a method that modulates levels of vWF or FVIII in an animal by contacting cells obtained from said animal with a binding moiety that specifically binds oligosaccharides that either have or lack a terminal α 2,3, linked sialic acid.

Therefore, the special technical feature linking the inventions of groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2 as it is not a shared or corresponding technical feature.

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The special technical feature of Group I is considered to be a method of modulating the levels of vWF or FVIII in an animal comprising administering an agent that increases ST3Gal-IV sialyltransferase activity in an animal.

The special technical feature of Group II is considered to be a method of modulating the levels of vWF or FVIII in an animal comprising administering an agent that decreases ST3Gal-IV sialyltransferase activity in an animal.

The special technical feature of Group III is considered to be an *in vitro* method of monitoring the efficacy of a method that modulates levels of vWF or FVIII in an animal by contacting cells obtained from said animal with a binding moiety that specifically binds oligosaccharides that have a terminal α 2,3, linked sialic acid.

The special technical feature of Group IV is considered to be an *in vitro* method of monitoring the efficacy of a method that modulates levels of vWF or FVIII in an animal by contacting cells obtained from said animal with a binding moiety that specifically binds oligosaccharides that have or a terminal α 2,3, linked sialic acid.

The special technical feature of group V is considered to be a eukaryotic cell comprising a non-naturally occurring mutation that results in a decrease in expression of the ST3Gal-IV allele(s).

The special technical feature of group VII is considered to be a eukaryotic cell comprising a non-naturally occurring mutation that results in an decrease in enzymatic activity of a ST3Gal-IV polypeptide expressed from a ST3Gal-IV allele(s).

Accordingly, groups I-VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file

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folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
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